

proposed rule that would eliminate the need for Forms FDA 3427 and 3429. However, because the proposed rule has not been finalized, we continue to include the forms in the burden estimate for this information collection.

The reclassification provisions of the FD&C Act serve primarily as a vehicle for manufacturers to seek

reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements applicable to that device type. If approved, petitions requesting classification from class III to class II or

class I provide an alternative route to market in lieu of premarket approval for class III devices. If approved, petitions requesting reclassification from class I or II, to a different class, may increase requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supporting data for reclassification petition—21 CFR 860.123	6	1	6	497	2,982
Supplemental Data Sheet	3427	6	1	6	1.5	9
General Device Classification Questionnaire	3429	6	1	6	1.5	9
Total	3,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on reclassification petitions received in the last 3 years, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

The burden estimate for this information collection has not changed since the last OMB approval.

Dated: February 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0263]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 6, 2018.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990-0263—Extension Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule) form.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, OMB, on the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103. The respondents for this collection are institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule) which is identical to 45 CFR part 46, subpart A.

Likely Respondents: Individuals, business or other for-profit, not for-profit institutions, Federal, State, Local or Tribal Governments.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption	14,000	2	0.5	14,000
Total				14,000

Terry S. Clark,
Asst Information Collection Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0260]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 7, 2018.

ADDRESSES: Submit your comments to *Sherette.Funn@hhs.gov* or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference., to *Sherette.funn@hhs.gov*, or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990-0260—Extension Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Abstract: Assistant secretary for Health, Office for Human Research

Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation. The purpose of the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) is to provide a uniform government-wide standard for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to apply regarding the protection of human subjects involved in research. The HHS codification of the Common Rule is at 45 CFR part 46 subpart A. The respondents for this collection are institutions engaged in such research. Institutional adherence to the Common Rule also is required by other federal departments and agencies that have codified or follow the Common Rule which is identical to 45 CFR part 46, subpart A.

Likely Respondents: Institutions engaged in nonexempt human subject's research.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.103(b)(4), .109(d)IRB Actions, .116 and .117 Informed Consent	6,000	39.33	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting ...	6,000	0.5	45/60	2,250
Total				1,138,230

Terry S. Clark,
Asst Information Collection Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a

meeting of the Board of Regents of the National Library of Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.